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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/836,075	04/21/1997	GEERT MAERTENS	INNS:004/KAM	5845

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EXAMINER	
ZEMAN, MARY K	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/836,075	MAERTENS ET AL.	
	Examiner	Art Unit	
	Mary K Zeman	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *01 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *75-85* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *75-85* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/1 6/16*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/1/04 has been entered.

Claims 75-85 are pending in this application. Applicant's arguments filed 6/1/04 have been fully considered but are not completely persuasive. Any rejection not repeated below has been withdrawn.

Information Disclosure Statement

The information disclosure statements filed 6/1/04 and 6/16/04 have been entered and considered. Initialed copies of the forms are enclosed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 75-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 75, the metes and bounds of the phrase "characterized by" in reference to a polynucleotide are unclear. It is unclear if this phrase in intended to be open or closed claim language, and what exactly the claimed polynucleotides are intended to encompass. What "characterizes" a nucleic acid sequence? The entire sequence? A portion of the sequence? Some pattern within the sequence? How is this characterization applied to other sequences or other polynucleotides? Applicant is encouraged to employ terms having well accepted legal definitions such as "comprising" "having" or "consisting of".

In claim 76, the metes and bounds of "part ii" are unclear. It is unclear if the five nucleotides must exist within the whole genomic sequence, or whether any 5 nucleotides that happen to contain a codon for Isoleucine, or Cysteine, or Valine etc are sufficient. Random hexamer polynucleotides (which contain all possible 6 nucleotide combinations) would appear to meet this last interpretation. The polynucleotide of (ii) is not required to encode a polyprotein.

It is unclear how claim 77 further limits claim 75. If the polynucleotide has the sequence of one of the listed SEQ ID NO, it should already have a determined sequence. It is unclear how to determine what sequence or SEQ ID NO: should have the specific codon identified- for example, which of the recited codons of claim 77 applies if SEQ ID NO: 43 is selected for the polynucleotide of claim 75? How is one of skill in the art intended to determine what sequences are covered by the claim?

The metes and bounds of claim 78 are entirely unclear at to what in encompasses, and how it further limits claim 75. Claim 76 appears to be much *broader* in scope than claim 75. In part (ii) it is unclear if the five nucleotides must exist within the whole genomic sequence, or whether any 5 nucleotides that happen to contain a codon for Isoleucine, or Cysteine, or Valine etc are sufficient. Random hexamer polynucleotides (which contain all possible 6 nucleotide combinations) would appear to meet this last interpretation. The polynucleotide of (ii) is not required to encode a polyprotein. If the polynucleotide has the sequence of one of the listed SEQ ID NO from claim 75, it should already have a determined sequence. It is unclear how to determine what sequence or SEQ ID NO: should have the specific codon identified- for example, which of the recited codons of claim 78 applies if SEQ ID NO: 43 is selected for the polynucleotide of claim 75? How is one of skill in the art intended to determine what sequences are covered by the claim?

The metes and bounds of claim 79 are unclear. It is unclear if the amino acid sequence selected should correspond to the polynucleotide sequence selected in claim 75. For example, if SEQ ID NO: 43 is selected for the polynucleotide of claim 75, what sequence should be selected from Claim 79? The corresponding amino acid sequence of SEQ ID NO: 44? The claim is not limited to this interpretation.

The metes and bounds of claim 80 are unclear- how is "a HCV 5' UR sequence" defined- as the entire sequence? a part thereof? What part? It would also appear that the limitation should read "5' UTR". How is "a HCV Core/E1 nucleic acid sequence" defined- as the entire sequence? a part thereof? What part? How is "a HCV NS4 nucleic acid sequence" defined- as the entire sequence? a part thereof? What part? How is "a HCV NS5B nucleic acid sequence" defined- as the entire sequence? a part thereof? What part?

The metes and bounds of claims 81-85 are unclear because it is unclear what the polynucleotides from claims 75-79 are, as set forth above.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 76, 78, and 80 and claims 81-85 in as far as they read on claims 76, 78 and 80 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

In view of the indefiniteness of the rejected claims, the broadest reasonable interpretation of the claims is being utilized herein. Claim 75 is being interpreted as a polynucleotide comprising at least the recited SEQ ID NO: Claims 76 and 78 are being interpreted as a polynucleotide comprising at least 5 nucleotides which also must encode one listed amino acid. Claim 77 is being interpreted as a polynucleotide which encodes a HCV polyprotein having at least one of the specified amino acids. Claim 79 is being interpreted as a polynucleotide encoding a polyprotein, and comprising a sequence which encodes one of the listed amino acid sequences. Claim 80 is being interpreted as a polynucleotide of at least 5 nucleotides according to claim 76 or 78 that also comprises some other HCV sequence as listed in the claim.

The specification discloses SEQ ID NO: 1, 3, 5 etc. odd numbers to 105, and sequences encoding SEQ ID NO: 107-207 which correspond to specific portions of HCV genomic sequences that fall within certain subtypes of HCV. Claims directed to these specific SEQ ID NO's would meet the written description provisions of 35 USC 112, first paragraph. However, claims 76 and 78 are directed to encompass any polynucleotide sequence (of at least five nucleotides) which happens to encode one of the listed amino acids. **None** of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

The basis for the written description rejection has been provided in previous actions.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 76, 77, 78, 80 and 81-85 are rejected under 35 USC 102(e) as being anticipated by Houghton et al. (US 5,350,671 previously of record.)

Houghton et al discloses a composite HCV polyprotein sequence at figure 66 which corresponds to the composite nucleotide sequence of Fig 62. This polyprotein discloses an amino acid sequence having at least an S at position 2646. Houghton's sequence also has A2719, E2751, D2752, L2756 and R2757. Houghton discloses polynucleotides, short and long, which encode HCV polyproteins and parts thereof. Houghton discloses vectors comprising the sequences, host cells comprising the vectors, and methods of making recombinant polypeptides. Houghton discloses peptides, long and short, which are portions of the polyprotein sequences disclosed. As the rejected

claims are unclear as to what exactly they encompass, Houghton also discloses multiple short polynucleotides of HCV each of which, at some point, encodes one of the amino acids listed in claims 76 and 78. As such, this reference meets the limitations of the rejected claims.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P Woodward can be reached on (571) 272 0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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MARY K. ZEMAN
PRIMARY EXAMINER